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United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-24

Marketing and
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Veterinary Services

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Biologics
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Subject: Guidance Document for Veterinary Biologics Derived from
Bioengineered Plants

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

The purpose of this notice is to inform all interested persons of the availability of a draft guideline entitled "Guidance for Industry: Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals."

II. BACKGROUND

The U.S. Department of Agriculture (USDA), in collaboration with the Food and Drug Administration (FDA), is announcing the availability of a draft guidance document entitled "Guidance for Industry: Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals" dated September 12, 2002. The draft guideline outlines important scientific questions and information that should be addressed when applying for a United States Veterinary Biological Product License for veterinary biologics derived from bioengineered plants.

Because the draft guidelines apply to veterinary biologics regulated by the Animal and Plant Health Inspection Service under the Virus-Serum-Toxin Act, we are requesting comments on the scope of the guideline so that we may include any relevant input on the draft in our discussions with the FDA.

This draft guidance document represents the agency's current thinking on this topic. It is being distributed for comment purposes only and is not intended for implementation at this time.

III. COMMENTS

Interested persons may submit comments or questions regarding this draft guidance document to Dr. Pat Foley, Center for Veterinary Biologics, 510 South 17th Street, Suite 104, Ames, IA 50010-8197. The deadline for comments on the draft is January 10, 2003.



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IV. DOCUMENT ACCESS

You may request a copy of this document by contacting Ms. Harriet Murphy, Center for Veterinary Biologics, Riverdale, Maryland, at 301-734-8245.

Persons with access to the Internet may obtain the document at one of several locations:

<http://www.aphis.usda.gov/vs/cvb/notices/bioplantguidancedoc.pdf>

<http://www.fda.gov/cber/guidelines.htm> or

<http://www.fda.gov/ohrms/dockets/default.htm>.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.

Director

Center for Veterinary Biologics